

### **REMARKS**

Claims 1-12, 23 and 24 are pending in the instant application. Applicants have hereinabove amended claims 1 and 9. Support for the amendments to claims 1 and 9 may be found, *inter alia*, in the subject specification on page 20, lines 5-16, especially lines 7-10. This Amendment does not involve any issue of new matter. Therefore, entry of this Amendment is respectfully requested such that claims 1-12, 23 and 24 will be pending and under examination.

### **Claim Objection**

The Examiner objected to claim 1 for the following alleged informalities. The Examiner stated that steps (b) and (c) recite the language 50% inhibitory concentration (IC50) of the analyte for the full length human AR or ARLBD. The Examiner suggested "50% inhibitory concentration (IC50) of the analyte for the full length human AR."

In response, applicants respectfully traverse. As described on page 1, paragraph (1), the invention set forth in the pending claims relates to a method for identifying androgen receptor (AR) modulators, i.e. analytes, which have full AR agonist or antagonist activity or mixed agonist activity. The invention is practiced by determining the binding of the analyte to a full length AR and comparing that determination to the binding of the analyte to the ligand binding domain of AR (ARLBD). The binding is determined by measuring the 50% inhibitory concentration (IC50) of each binding event. For example, the binding of the analyte to full length AR results in the first IC50 value and the binding of the analyte to the ligand binding domain of AR (ARLBD) results in the second IC50 value. The first IC50 value is then compared to the second IC50 value in order to determine whether the analyte has full AR agonist or antagonist activity or mixed agonist activity. Claim 1 recites in step (b) the method for obtaining the first IC50 and in step (c) the method for obtaining the second IC50. Therefore, applicants respectfully contend that claim 1 need not be amended as the Examiner suggested. In light of the above remarks, applicants respectfully request that the Examiner reconsider and withdraw this ground of objection.

**Claim Rejection Under 35 U.S.C. §112, first paragraph**

The Examiner rejected claims 1-3, 5-12 and 23-24 under 35 U.S.C. §112, first paragraph, as allegedly failing to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The Examiner stated that the specification does not reasonably provide enablement for a second IC50 which is about five-fold less than the first IC50 for the mixed agonist. However, the Examiner conceded that the specification is enabling for the second IC50 15-fold greater than the first IC50 for the mixed AR agonist.

In response, applicants respectfully traverse. Nevertheless, applicants, without conceding the correctness of the Examiner's position and to expedite prosecution of the subject application, have herein amended claims 1 and 9 to address the Examiner's rejection. Claims 1 and 9, as amended, recite in part: "a second IC50 which is five-fold greater than the first IC50." This amendment is fully supported on page 20, lines 5-16, especially lines 7-10.

In view of the above remarks, applicants maintain that claim 1, and claims 2-12, 23 and 24 which depend therefrom, satisfy the enablement requirement of 35 U.S.C. §112, first paragraph. Accordingly, applicants respectfully request that the Examiner reconsider and withdraw this ground of rejection.

**Summary**

For the reasons set forth hereinabove, applicants respectfully request that the Examiner reconsider and withdraw the various grounds of objection and rejection, and earnestly solicit allowance of the pending claims.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone her at the number provided below.

No fee is deemed necessary in connection with the filing of this Amendment. However, if any fee is required, authorization is hereby given to charge the large entity amount of such fee to Deposit Account No. 13-2755 referencing attorney docket number 21506YP.

Respectfully submitted,

By Maria V. Marucci  
Maria V. Marucci  
Reg. No. 59,895  
Attorney

MERCK & CO., INC.  
P.O. Box 2000  
Rahway, New Jersey 07065-0907  
(732) 594-5738